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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,831	10/11/2007	Sung Oh Chung	HANOL-13074	1454

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EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	PAPER NUMBER
1633	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,831	CHUNG ET AL.	
	Examiner	Art Unit	
	MARIA LEAVITT	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01-05-2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Status of claims. Claims 1-5 are pending. Claims 6-7 have been cancelled by Applicants' amendment filed on 04-19-2010.

Applicants' election without traverse of Group I, i.e. claims 1-5, drawn to a gene which is selected from a polynucleotide as set forth in SEQ ID NO: 1 or a polynucleotide encoding a γ-butyrobetaine hydroxylase as set forth in SEQ ID NO: 2.

The requirement is deemed proper and made Final.

Therefore, claims 1-5 are currently being examined to which the following grounds of rejection are applicable.

Priority

The instant application is granted the benefit of priority for the foreign application 10-2004-0013032 filed in the Republic of Korea on February 26, 2004 as requested in the declaration file 08/28/2006. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119(a)-(d), which papers have been placed of record in the file. Filing on 08-28-2006 of a certified non-translated copy of the Korean Application 10-2004-0013032 is acknowledged.

Should Applicants provide a certified translation of their foreign priority document to overcome the prior art rejection, Applicants should indicate whether the priority application is identical to the instant application, or if the priority application contains additional disclosure. If there is additional disclosure, a brief summary should be provided. Applicants should also indicate where support for each of the claim limitations (for the independent claims) can be found in the translated priority document by page and line number. If support is not found *in ipsis verbis*, clarification on the record may be helpful to the examination process.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 01-05-2010 is not in compliance with the provisions of 37 CFR 1.97. The following references have not been considered by the examiner, as indicated on Form PTO 1449.

a) Reference 2, JP S57-39791 (Date of Publication 1982-05-03), has not been considered as an English translation of the JP S57-39791 has not been provided.
b) Reference 2, Galagan et al 2003, pp. 859-868, has not been considered as a legible copy of the publication has not been provided.
c) Reference 4, Frederic et al., 1998, pp. 50-510, has not been considered as a legible copy of the publication has not been provided.
d) Reference 5, Bach et al 1982, pp. 583-596, has not been considered as a legible copy of the publication has not been provided.
e) Reference 6, Sandor et al., 1988, pp. 17-27, has not been considered as a legible copy of the publication has not been provided.

All other documents in said Information Disclosure statement were considered as noted by the Examiner initials in the copy attached hereto.

Claim Objections

Claim 1 is objected to because of the following informalities: At lines 1 and 2 of claim 1 the abbreviation SEQ ID. NO: is misspelled. Appropriate correction is required.

35 USC 101-non-statutory subject matter

35 U.S.C. §101 states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected under 35 USC §101 because the claimed invention is directed to

non-statutory subject matter.

Claim 1 recites the phrase "a gene". As written, claims 1-5, do not sufficiently distinguish over cells on their own right that exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" as taught at ¶ [0036] of the published application. See MPEP 2105.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are directed to a polynucleotide "represented by" SEQ ID NO: 1 or a polynucleotide encoding a γ-butyrobetaine hydroxylase "represented by" SEQ ID NO: 2. It is unclear if the phrase "represented by" should be interpreted narrowly to encompass only materials that have a structure identical to the SEQ ID NO: or if the phrase should be interpreted broadly to encompass materials which have a structure "similar" to the SEQ ID NO:. The metes and bounds are not clearly set forth. Amending the claims to recite "as set forth" would be remedial.

Claims 2-5 are indefinite insofar as they depend from claim 1.

Claim Rejections - 35 USC § 112-Deposit Requirement

To the extent that claims 5 depending on claim 3 requires an *Escherichia coli* transformed with a recombinant vector comprising with Accession No. KCCM-10557, the following rejection applies.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The 3 is directed to a recombinant vector which has accession number KCCM-10557. Additionally, claim 5 is drawn to an *E. coli* transformed with said recombinant vector. As such, the claim is directed to a product that is encompassed by the definitions for biological material set forth in 37 C.F.R.§1.801. With regard to making the specific embodiment recited the claim 3, the specification provides only a vague statement that a " pT7-BBH2 vector (*Escherichia coli* DH5α CJ2004), which is constructed according to the present invention for expression of a polynucleotide encoding γ-butyrobetaine hydroxylase derived from *Neurospora crassa*, was deposited at an international depository authority, the Korean Culture Center of Microorganisms (KCCM) on Jan. 27, 2004, an d assigned accession number KCCM-10557" (¶ [0027] of the published application). However, the complexity of a transforming vector precludes independent

derivation of another transforming vector with substantially identical characteristics absent a full disclosure of the characteristics that define the vector (*i.e.*, the full sequence of the vector) because the specific structural features that define the vector are not disclosed in the application. In the absence of such a disclosure, the skilled artisan would not know how to make the pT7-BBH2 vector introduced into *Escherichia coli* DH5α CJ2004. Although the pUC19 vector is disclosed in the art (see Tabor *et al.* ,1985, *Proc Natl Acad Sci U S A. pp.1074-8.*), the disclosure in the art also fails to provide a complete sequence for the vector,. In view of the fact that a complete disclosure of the pT7-BBH2 vector sequence is not available, the skilled artisan would not know how to make the vector pT7-BBH2.

Additionally, the specification lacks complete deposit information for the deposit of Escherichia coli α CJ2004 (Accession No. KCCM-10557) as required in claim 5. Because it is not clear that the properties of this strain are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the best mode disclosed by the specification requires the use of this specific strain, a suitable deposit for patent purposes is required.

It is noted that Applicant has deposited the biological materials (p. 15, lines 14-17 of the specification), but there is no indication in the specification as to public availability.If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of the deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be replaced if

viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of the deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become non-viable or non-replicable.

In addition, a deposit of the biological material that is capable of self-replication either directly or indirectly must be viable at the time of the deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1)The name and address of the depository;
2)The name and address of the depositor;
3)The date of deposit;
4)The identity of the deposit and the accession number given by the depository;
5)The date of the viability test;
6)The procedures used to obtain a sample if the test is not done by the depository; and

7)A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the cell line described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 U.S.C. § 102

The claimed invention is directed to a polynucleotide encoding gamma-butyrobetaine hydroxylase originating from *Neurospora crassa* (claim 1), a recombinant vector comprising the polynucleotide (claim 2), and a transformant transformed with the recombinant vector, gamma-butyrobetaine hydroxylase encoded by the polynucleotide of SEQ ID NO: 1. The limitation of "a polynucleotide" a recited in claim 11, lines 1 and 2, is broadly interpreted as nucleic acid molecules encompassing the full length or any portion of SEQ ID NO: 1 or SEQ ID NO: 2. To the extent that the instant claims embrace a gene coding for any portion of SEQ ID NO: 1 or SEQ ID NO: 2, the following rejection applies

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 4 are rejected under 35 U.S.C. §102(b) as being anticipated by Timberlake et al., (US Application NO: 12,336,504, Priority date September 23, 1999)

Timberlake et al., teaches nucleic acid molecules comprising the *E. nidulans* genome isolated from a sample of filamentous fungus identified as *Aspergillus nidulans*(¶ [0005] of the published application). Specifically, Timberlake discloses a polynucleotide sequence identified as SEQ ID NO: 1369 of 3568 nucleotides in length having 28.9% sequence homology to the instant nucleotide sequence of SEQ ID NO:1 (See Score Result 4 on the attached search print out for application 10590831). Moreover, Timberlake et al., teaches recombinant vectors comprising a nucleic acid of interest and host cells transformed with the expression encoding a protein of interest (¶ [0033] of the published application).

Absent evidence to the contrary, Timberlake et al., teaches two nucleotide or more nucleotides that are portions of the claimed nucleic acid sequence of SEQ ID NO:1, which falls within the scope of claim 1.

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Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Galagan et al., (Nature 422:859-868 April, 2003; see SCORE Search Results Details for Application 10590831 and Search Result 20100622_105233_us-10-590-831-2.rup).

Galagan et al., teaches a nucleic acid molecules encoding an amino acid sequence identified as GeneID 3875737 having 100% sequence homology to the claimed amino acid sequence of SEQ ID NO:2.

Absent evidence to the contrary, Galagan et al., teaches nucleotide acid molecules encoding an amino acid sequence having 100% homology to the amino acid sequence of SEQ ID

NO:2.

Conclusion

Claims 1-5 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maria Leavitt/

Maria Leavitt
Primary Examiner, Art Unit 1633